

Amend the specification as follows.

AMEND paragraph [0002] of the application as filed on September 22, 2003 and subsequently amended as follows: (effectively reversing the amendment)

This invention relates to a concentrated hormone pharmaceutical composition to be used in the ~~manufacture of products for~~ production of hormone replacement therapies.

DELETE paragraphs [00016.1], [00016.2], and [00016.3] added to the application in the amendment dated August 4, 2005.

DELETE paragraph [00017.1] added to the application in the amendment dated August 4, 2005.

AMEND paragraph [0018] of the application as follows:

The invention offers at least one of the following advantages:

- ~~provides a concentrated pharmaceutical composition~~ a system of concentrated pharmaceutical compositions that is easy to use and saves time and money to the pharmacies dealing with BHRT pharmaceutical ~~products.~~ products;
- ~~provides a pharmaceutical composition having a higher concentration of hormone than the concentration found in the BHRT pharmaceutical products of the prior art.~~
- ~~provides a pharmaceutical composition that can be used by the compounding pharmacist safely, accurately, quickly.~~
- ~~provides an inexpensive pharmaceutical composition with individualized BHRT products such as ointments, creams, gels, or pastes.~~ pastes; and
- provides a color-coded hormone pharmaceutical composition.

AMEND paragraph [0022] of the application as follows (effectively reversing the subsequent amendment dated August 4, 2005):

~~In one aspect, the present invention provides~~ The present invention relates to a concentrative hormone pharmaceutical composition comprising: about 3.5 to about 80% of at least one hormone; and about 20 to about 96.5% of at least one solvent. Preferably, the concentrated hormone pharmaceutical composition comprises about 25.1 to about 80% of said at least one hormone; and about 20 to about 74.9% of said at least one solvent from about 0.6 to about 80% of at least one hormone; from about 20 to about 90.4% of at least one solvent, and optionally a pharmaceutically acceptable carrier.

DELETE paragraphs [00022.1] to [0022.12] added into the application in the amendment dated August 4, 2005.

ADD BACK the following paragraphs (paragraphs [00023 to 00033] of the application as filed) after paragraph [00022]:

[00023] In the preferred embodiment, the concentrated hormone pharmaceutical composition is chosen from estradiol, estrone, estriol, testosterone, DHEA, pregnenolone, progesterone, or combination thereof.

[00024] The invention also relates to a concentrated hormone pharmaceutical composition comprising:

- from about 0.6 to about 50% of at least one hormone;
- from about 50 to about 90.4% of at least one solvent, and
- optionally a pharmaceutically acceptable carrier
- wherein the at least one hormone is chosen from estriol, estradiol, or combination thereof.

[00025] The at least one hormone is a combination of estriol and estradiol in a ratio of 5:5, 6:4, 7:3, 8:2, or 9:1.

[00026] Furthermore, the invention concerns a concentrated hormone pharmaceutical composition comprising:

- from about 0.6 to about 50% of at least one hormone;
- from about 50 to about 90.4% of at least one solvent, and
- optionally a pharmaceutically acceptable carrier

wherein the at least one hormone is chosen from estriol, estradiol, estrone, or combination thereof.

[00027] The at least one hormone is a combination of estriol, estradiol, and estrone in a ratio of 5:4:1, 6:3:1, 7:2:1, or 8:1:1.

[00028] Furthermore, the invention concerns a concentrated hormone pharmaceutical composition comprising:

- from about 0.8 to about 80% of at least one hormone;

- from about 20 to about 90.2% of at least one solvent, and
- optionally a pharmaceutically acceptable carrier
- wherein the at least one hormone is testosterone.

[0029] In addition, the invention concerns a concentrated hormone pharmaceutical composition comprising:

- from about 8 to about 90% of at least one hormone;
- from about 10 to about 92% of at least one solvent, and
- optionally a pharmaceutically acceptable carrier
- wherein the at least one hormone is progesterone.

[00030] Furthermore, the invention concerns to a color-coded concentrated hormone pharmaceutical.

[0031] Furthermore, the invention concerns a method for producing a concentrated hormone pharmaceutical composition, the method comprising the steps of:

- measuring at least one hormone, a solvent and/or optionally a carrier by using an electronic balance in a clean room;
- combining the ingredients of step a by using an industrial scale mixer to ensure thorough mixing; and
- running the mixture of step b through a large-scale ointment mill or homogenizer to decrease the particle size of the drug, and
- optionally, heating the concentrate to facilitate the formation of a solution,
- wherein the hormone concentration is from about 0.6 to about 80%.

[00032] Furthermore, the present invention concerns a concentrated hormone pharmaceutical composition comprising:

- at least one hormone;
- optionally a powdered base;

wherein the at least one hormone is chosen from estriol, estradiol, estrone, or combination thereof; and wherein the composition is in a powdered form.

[00033] Finally, the invention concerns a kit for producing a liquid or semi-solid concentrated hormone pharmaceutical composition, the kit comprising:

- at least one hormone;
- at least one solvent, and
- optionally a pharmaceutically acceptable carrier,
- wherein each element is packet in separated graduated dispensing devices.

AMEND paragraph [00036] of the application as follows (effectively reversing the subsequent amendment of August 4, 2005):

The present invention concerns a concentrated hormone pharmaceutical composition comprising: about 3.5 to about 80% of at least one hormone; and about 20 to about 96.5% of at least one solvent at least one hormone and at least one solvent, and optionally a pharmaceutically acceptable carrier, wherein the weight concentration of the at least one hormone in said composition is equal or greater than 0.6%.

AMEND paragraph [00052] of the application as follows (effectively reversing the amendment of August 4, 2005):

The present invention also concerns a concentrated hormone pharmaceutical composition comprising: about 3.5 to about 100% of at least one hormone selected from the group consisting of estriol, estradiol, and combinations thereof; and about 0 to about 96.5% of at least one solvent from about 0.6 to about 50% of at least one hormone; and about 50 to about 90.4% of at least one solvent, and optionally a pharmaceutically acceptable carrier, wherein the at least one hormone is chosen from estriol, estradiol, or combination thereof.

AMEND paragraph [00054] of the application as follows (effectively reversing the amendment of August 4, 2005):

In addition, the present invention concerns a concentrated hormone pharmaceutical composition comprising: about 3.5 to about 100% of at least one hormone selected from the group consisting of estriol, estradiol, estrone, and combinations thereof; and about 0 to about 96.5% of at least one solvent from about 0.6 to about 50% of at least one hormone; and about 50 to about 90.4% of at least one solvent, and optionally a pharmaceutically acceptable carrier, wherein the at least one hormone is chosen from estriol, estradiol, estrone, or combination thereof.

AMEND paragraph [0054] of the application as follows (effectively reversing the amendment of August 4, 2005):

Furthermore, the present invention concerns a concentrated pharmaceutical composition comprising ~~about 6.4 to about 80% of testosterone; and about to about 93.6^ of at least one solvent~~ from about 0.8% to about 80% of at least one hormone; from about 20 to about 90.2% of at least one solvent, and optionally a pharmaceutically acceptable carrier, wherein the at least one hormone is testosterone.

AMEND paragraph [0055] of the application as follows (effectively reversing the amendment of August 4, 2005):

The invention also concerns a concentrated hormone pharmaceutical composition comprising: ~~about 10.1 to 90% of progesterone; and about 10 to about 89.9% of at least one solvent~~ from about 8 to about 90% of at least one hormone; and from about 10 to about 92% of at least one solvent, and optionally a pharmaceutically acceptable carrier, wherein the at least one hormone is progesterone.